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UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

BING LI, Individually and on Behalf of All Others Similarly Situated, Plaintiff, v. AETERNA ZENTARIS, INC., DAVID A. DODD, JUERGEN ENGEL, DENNIS TURPIN, JUDE DINGES, RICHARD SACHSE, and PAUL BLAKE, Defendants,	Case No.: 3:14-CV-07081-PGS CLASS ACTION **AMENDED CLASS ACTION COMPLAINT FOR VIOLATIONS OF THE FEDERAL SECURITIES LAWS** JURY TRIAL DEMANDED

Lead Plaintiffs Gregory Vizirgianakis, Phong Thomas Dinh, and Jamshid Khodavandi ("Plaintiffs"), by and through their attorneys, allege the following upon information and belief, except as to those allegations concerning Plaintiffs, which are alleged upon personal knowledge. Plaintiffs' information and belief is based upon, among other things, their counsel's investigation, which includes without limitation: (a) review and analysis of regulatory filings made by Aeterna Zentaris, Inc. ("Aeterna" or the "Company"), with the United States Securities and Exchange Commission ("SEC"); (b) review and analysis of press releases and media reports issued by and disseminated by Aeterna; (c) review of other publicly available information concerning Aeterna; and (d) discussions with an FDA regulatory and drug development expert familiar with the relevant facts herein. Plaintiffs believe that substantial evidentiary support will exist for the allegations set forth herein after a reasonable opportunity for discovery.

NATURE OF THE ACTION

1. This is a class action on behalf of persons or entities that purchased or otherwise acquired Aeterna securities during the period from August 30, 2011 through November 6, 2014, both dates inclusive (the "Class Period"). Plaintiffs seek to pursue remedies under Sections 10(b) and 20(a) of the Securities Exchange Act of

1934 (the "Exchange Act") and Rule 10b-5 promulgated thereunder, against the Company and certain of its top officials.

2. Aeterna is a specialty biopharmaceutical company engaged in developing novel treatments in endocrinology and oncology. The Company's pipeline is comprised of compounds at various stages of development, none of which have been approved for commercial sale to the public.

3. One of Aeterna's primary drug development candidates was AEZS-130 (marketing name: Macrilen, and was also known as "Solorel" and "macimorelin"). AEZS-130 is a growth hormone stimulator intended to diagnose whether a person has adult growth hormone deficiency ("AGHD").

4. Aeterna acquired the rights to AEZS-130 from Ardana Bioscience Ltd. in 2009 for $232,000. Ardana had partially completed a Phase 3 study of AEZS-130, but suspended the study when it ran into financial difficulties. Aeterna acquired the rights to AEZS-130 along with this study from Ardana.

5. In an effort to gain FDA approval for commercialization of AEZS-130, Aeterna initiated discussions with the FDA on how to complete the Phase 3 study. FDA and Aeterna agreed that Aeterna could complete the study and file a New Drug Application ("NDA") with the FDA by enrolling an additional 50 subjects.

6. To formalize this agreement, on December 20, 2010, Aeterna agreed to a Special Protocol Assessment ("SPA") with the FDA. The SPA is a binding agreement that governed the design, subject inclusion criteria, minimum number of subjects, clinical endpoints, and specific statistical analyses for Aeterna's Phase 3 study of AEZS-130. In other words, once Aeterna reached an agreement with the FDA on the SPA, Aeterna was bound to conduct the Phase 3 trial and analyze the data collected from it in accordance with the terms established by the SPA.

7. A successful Phase 3 study conducted in strict accordance with the terms of the SPA forms the primary basis for any claim by Aeterna that AEZS-130 has shown "efficacy" that will be part of any New Drug Application ("NDA").

8. During the Class Period, defendants repeatedly touted that AEZS-130 successfully met the primary endpoint of the Phase 3 study in accordance with the terms of the SPA. Specifically, defendants issued numerous press releases and other statements indicating that AEZS-130's Phase 3 trial, conducted under the SPA, showed that the drug was effective for evaluating AGHD in accordance with the protocol agreed to in the SPA.

9. Defendants' claims that the Phase 3 study showed AEZS-130 to be effective for diagnosing AGHD was false. In truth, Aeterna's Phase 3 trial actually ***failed*** to show that AEZS-130 was an effective diagnostic test for AGHD. In fact,

AEZS-130 was only "effective" when Aeterna manipulated the data and threw out the results from two subjects from the Phase 3 study, in clear violation of the protocol Aeterna agreed to in the SPA.

10. Aeterna's senior officers attended a pre-NDA meeting with the FDA before submitting the NDA in November 2013, and were present when the FDA stated that it disagreed with Aeterna's decision to exclude from the final dataset two AGHD patients that Aeterna believed were not confirmed cases. The FDA disagreed with Aeterna because it is improper to exclude subjects from the final database once the trial has concluded, the dataset locked, and the results analyzed. Aeterna's decision to exclude the subjects was made only after Aeterna had completed the per protocol statistical analysis and learned that AEZS-130 had not proven effective.

11. Only after sifting through and manipulating the data in a desperate attempt to show efficacy did Aeterna determine that it was appropriate to exclude the two AGHD patients from the final dataset. By running alternative statistical analyses, Aeterna determined it could make a case that AEZS-130 was effective by excluding two confirmed AGHD patients that had not been correctly diagnosed as having AGHD after being given AEZS-130. The FDA, accustomed to such maneuvering, made clear that it did not accept Aeterna's after-the-fact exclusion of two patients from the dataset.

12. Notwithstanding having been told by the FDA that its plan to exclude the two AGHD subjects from the final dataset was unacceptable and a violation of the SPA, Aeterna submitted its NDA with a final dataset and statistical analysis that excluded the two AGHD patients. Aeterna knew that its NDA was doomed, yet pressed ahead anyway because its primary goal was to raise millions of dollars from investors based on its false claims that AEZS-130 had proven effective in diagnosing AGHD.

13. In a series of public announcements from August 30, 2011 through March 21, 2014, Aeterna continually misrepresented that the AEZS-130 Phase 3 study had met its primary endpoint for efficacy and that AEZS-130 had proven effective according to the parameters of the SPA.

14. Based on the strength of the "successful" Phase 3 trials for AEZS-130 that appeared certain to lead to FDA approval and large profits, Aeterna sold nearly $75.0 million of its common stock to the investing public during the Class Period.

15. Subsequently on November 6, 2014, the U.S. Food and Drug Administration ("FDA") denied Aeterna's application to market the AEZS-130 publicly, in major part because Aeterna excluded from its statistical analysis the results of two of the subjects enrolled in the study, in violation of the parameters of the SPA.

16. When Aeterna announced publicly that the FDA denied Aeterna's NDA for AEZS-130 because Aeterna's statistical analysis failed to abide by the SPA and excluded subjects that the protocol required be included, Aeterna's stock price plummeted on heavy volume to close at $0.65 per share, a decline of almost 50% from the previous day's closing of $1.29 per share.

JURISDICTION AND VENUE

17. The claims asserted herein arise under and pursuant to Sections 10(b) and 20(a) of the Exchange Act, 15 U.S.C. §§ 78j(b), 78b-1 and 78t(a), and Rule 10b-5 promulgated thereunder by the SEC, 17 C.F.R. §240.10b-5.

18. This Court has jurisdiction over the subject matter of this action pursuant to Section 27 of the Exchange Act (15 U.S.C. § 78aa) and 28 U.S.C. § 1331.

19. Venue is proper in this Judicial District pursuant to Section 27 of the Exchange Act (15 U.S.C. § 78aa) and 28 U.S.C. § 1391(b), because Aeterna's common stock traded on the NASDAQ stock exchange and at times relevant to this complaint, Aeterna maintained an office in this District.

20. In connection with the acts, conduct, and other wrongs alleged in this Complaint, Defendants, directly or indirectly, used the means and instrumentalities of interstate commerce, including but not limited to, the United States mails,

interstate telephone communications and the facilities of the national securities exchange.

PARTIES

21. Lead Plaintiff Gregory Vizirgianakis purchased Aeterna securities at artificially inflated prices during the Class Period and has been damaged thereby. His PSLRA certification was previously filed with this Court and is incorporated by reference.

22. Lead Plaintiff Phong Thomas Dinh purchased Aeterna shares at artificially inflated prices during the Class Period and has been damaged thereby. His PSLRA certification was previously filed with this Court and is incorporated by reference.

23. Lead Plaintiff Jamshid Khodavandi purchased Aeterna shares at artificially inflated prices during the Class Period and has been damaged thereby. His PSLRA certification was previously filed with this Court and is incorporated by reference.

24. Defendant Aeterna Zentaris, Inc. is a Canadian corporation with its principal place of business at 1405 Blvd. du Parc-Technologique, Quebec City, Quebec, Canada GIP 4P5, and at times relevant to this complaint up until the present date, maintained offices at 25 Mountainview Blvd., Suite 203, Basking Ridge, NJ

07920, through its wholly owned subsidiary Aeterna Zentaris, Inc., a Delaware corporation. During the Class Period, Aeterna's common stock was actively traded on NASDAQ, under the ticker "AEZS."

25. Defendant Juergen Engel ("Engel") was the Company's President and CEO from September 2008 to April 2013. Engel had personal knowledge of the statistical analysis that Aeterna submitted to the FDA and was aware that it violated the statistical analysis plan agreed to with the FDA in the SPA. On information and belief Engel would have personally attended the pre-NDA meeting with the FDA and been present when the FDA stated that it disagreed with Aeterna's decision to exclude the two AGHD patients that Aeterna believed were not confirmed cases. Engle was quoted making false statements in the August 30, 2011 press release that AEZS-130 had proven effective according to the parameters of the SPA. He also signed each false and misleading Form 20-F during the Class Period until his departure in April 2013.

26. Defendant David A. Dodd ("Dodd") has served as the Company's President and CEO since April 2013. Prior to joining Aeterna as President and CEO, Dodd undertook a thorough review of Aeterna's pipeline of drugs under development. This includes reviewing the FDA file for AEZS-130, which would

have quite clearly revealed FDA's position that it believed Aeterna's exclusion of two AHGD patients from the final dataset violated the terms of the SPA.

27. Defendant Dennis Turpin ("Turpin") has been the Company's CFO and a Senior Vice President since August 2007.

28. Defendant Jude Dinges ("Dinges") has been the Company's Chief Commercial Officer and a Senior Vice President since November 2013.

29. Defendant Paul Blake ("Blake") was the Company's Chief Medical Officer from August 2007 until early 2014. As Chief Medical Officer, Blake had intimate knowledge of the AEZS-130 clinical study results and the statistical analysis that Aeterna had submitted to the FDA and was aware that it violated the statistical analysis plan agreed to with the FDA in the SPA. As Chief Medical Officer, Blake was the primary person responsible for explaining to the FDA at the pre-NDA meeting and in other communications Aeterna's rationale for excluding the two AGHD patients from the final dataset. Blake personally attended the pre-NDA meeting with the FDA and was present when the FDA stated that it disagreed with Aeterna's decision to exclude the two AGHD patients that Aeterna believed were not confirmed cases.

30. Defendants Dodd, Engel, Turpin, Dinges, and Blake are collectively the "Individual Defendants."

DETAILED ALLEGATIONS OF MISCONDUCT

Background

31. Aeterna is a specialty biopharmaceutical company engaged in developing treatments in endocrinology and oncology. The Company's pipeline is comprised of compounds at various stages of development, none of which have been approved for commercial sale to the public.

32. AEZS-130, until recently, was the Company's drug which was most advanced on the path to commercialization. AEZ-130 is an orally-administered drug designed primarily to evaluate and diagnose whether a person has AGHD.

33. The development of AEZS-130 was first initiated by Ardana Bioscience Ltd ("Ardana") in 2007. Due to financial problems at Ardana, Aeterna was able to acquire all rights to AEZS-130 from Ardana on June 8, 2009 for $232,000, including all of the clinical data and related assets comprising Ardana's incomplete Phase 3 clinical trial of AEZS-130.

34. In the process of purchasing the rights to AEZS-130 from Ardana, Aeterna performed a thorough due diligence investigation on AEZS-130, including carefully evaluating the data for the incomplete Phase 3 clinical trial that Ardana had initiated. Specifically, the data showing whether each subject enrolled in Ardana's

study was properly classified and met the inclusion and exclusion criteria established in the SPA was available for review by Aeterna.

35. Indeed, defendant Dodd admitted on a November 7, 2014 investor conference call that Aeterna evaluated the data obtained from Ardana's Phase 3 study ***before*** it decided to proceed with the Phase 3 study of AEZS-130 and ***before*** it entered into the SPA with the FDA.

36. On October 19, 2009, Aeterna announced that it would complete the Phase 3 study of AEZS-130, which Ardana had started, and that it was in discussion with the FDA regarding how to best complete the Phase 3 trial.

The Special Protocol Assessment

37. On December 20, 2010, Aeterna announced that it had agreed to a Special Protocol Assessment ("SPA") with the FDA for the completion of the Phase 3 study for AEZS-130. This meant that AEZS-130's Phase 3 trial must be conducted, and its data analyzed, in accordance with the clinical protocol and statistical analysis plan set forth in the SPA. If the Phase 3 trial was conducted pursuant to the SPA and the results met the objectives outlined in the SPA, the FDA would then have accepted the efficacy of AEZS-130.

38. A SPA is binding on both the sponsor (i.e. Aeterna) and the FDA, and may not be changed except by written agreement of both the sponsor and the FDA.

If the sponsor deviates from the parameters of the SPA without obtaining approval from the FDA, the FDA will interpret that as the sponsor's understanding that the agreement is now void.

39. A critical part of the SPA is the "statistical analysis plan" ("SAP"), which governs the planned statistical analysis of a clinical study. The SAP defines all the statistical output from the study which will be included in the clinical results, and includes specific procedures for the statistical analyses of the primary and secondary endpoints and other data.

The Phase 3 Study

40. The Phase 3 study for AEZS-130 consisted of two parts: the first part of the study was conducted by Ardana, and the second part by Aeterna.

41. According to Aeterna's December 20, 2010 press release, the part of the study completed by Ardana included: "42 patients with confirmed AGHD or multiple pituitary hormone deficiencies and a low insulin-like growth factor-I" and "[a] control group of 10 subjects without AGHD were matched to patients for age, gender, body mass index and (for females) estrogen status." (emphasis added).

42. The effectiveness of AEZS-130 was then to be compared to a drug that was already on the market, known as GHRH.

43. In 2008, however, GHRH was removed from the market, and therefore when Aeterna took over the Phase 3 study of AEZS-130, the comparator drug was no longer in existence.

44. Aeterna and the FDA then reached agreement on a SPA, which called for, among other revisions, the following changes to Adarna's existing study in light of GHRH being pulled from the market:

- An additional 30 normal controls subjects to be enrolled to match the AGHD patients from the original cohort;
- An additional 20 subjects be enrolled - 10 AGHD patients and 10 matched normal control subjects;
- The entire database would therefore include approximately 100 patients (52 from the earlier Ardana study and 50 from Aeterna's part of the study).

Aeterna Touts "Successful" Phase 3 Study

45. On August 30, 2011, Aeterna issued a press release announcing "favorable top-line results" of its "completed Phase 3 study" of AEZS-130. Aeterna also stated in the press release that "***[t]he parameters of the study...were achieved as agreed to with FDA under our Special Protocol Assessment (SPA). Importantly,***

the primary efficacy parameters show that the study achieved both specificity and sensitivity at a level of 90% or greater." (emphasis added).

46. In Aeterna's year 2011 Form 20-F, filed with the SEC on March 28, 2012, the Company stated:

- Our lead program in endocrinology, a Phase 3 trial ***under a Special Protocol Assessment ("SPA")*** obtained from the FDA with AEZS-130 as an oral diagnostic test for adult growth hormone deficiency ("AGHD"), ***has been completed with positive results***.
- On August 30, 2011: We reported favorable top-line results for the completed Phase 3 study for AEZS-130 as a first oral diagnostic test for AGHD. We also announced our intention to meet with the FDA for the future filing of a New Drug Application ("NDA"). The results showed that AEZS-130 reached its primary endpoint demonstrating >90% area-under-the-curve ("AUC") of the Receiver Operating Characteristic ("ROC") curve, which determines the level of specificity and sensitivity of the product.
- ***The parameters of the study were achieved as agreed to with the FDA under our SPA.*** Importantly, the primary efficacy parameters showed that the study achieved both specificity and sensitivity at a level of 90% or greater.

(emphasis added).

47. In connection with this Form 20-F, Defendants Engel and Turpin signed Sarbanes-Oxley ("SOX") certifications certifying that: "Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report[.]"

48. On June 26, 2012, Aeterna issued a press release announcing the final results of the Phase 3 drug trial with respect to AEZS-130. The press release stated in relevant part:

> Aeterna Zentaris Inc. (NASDAQ: AEZS) (TSX: AEZ) (the "Company") today announced that final Phase 3 results for its oral ghrelin agonist, AEZS-130, show that ***the drug is safe and effective in diagnosing adult growth hormone deficiency (AGHD)***.

49. Aeterna's Form 20-F for the year 2012, filed with the SEC on March 22, 2013, stated in relevant part:

- On August 30, 2011, we announced favorable top-line results of our completed Phase 3 study with AEZS-130 as a first oral diagnostic test for AGHD. The results showed that AEZS-130 had reached its primary endpoint demonstrating >90% area-under-the-curve ("AUC") of the Receiver Operating Characteristic ("ROC") curve, which determines the level of specificity and sensitivity of the product. ***Importantly, the primary efficacy parameters show that the study achieved both specificity and sensitivity at a level of 90% or greater.***

- On June 26, 2012, we announced that the final results from a multicenter, open-label Phase 3 trial for AEZS-130 showed that the drug is ***safe and effective*** in diagnosing AGHD.

- On October 18, 2012, we announced that results from a multicenter open-label Phase 3 trial for AEZS-130 demonstrated that the drug is ***safe and effective*** in diagnosing AGHD.

50. The statements in Aeterna's year 2012 Form 20-F described above were repeated in Aeterna's year 2013 Form 20-F, filed with the SEC on March 21, 2014.

51. In connection with the year 2012 Form 20-F, Defendants Engel and Turpin signed Sarbanes-Oxley certifications certifying that: "Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report[.]"

52. In connection with the year 2013 Form 20-F, Defendants Dodd and Turpin signed Sarbanes-Oxley certifications certifying that: "Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report[.]"

53. Each of the statements set forth above in Aeterna's August 30, 2011 and June 26, 2012 press releases and in each of its Form 20-Fs and accompanying SOX certifications for fiscal years 2011-2013 (filed March 28, 2012, March 22, 2013 and March 21, 2014), were materially false and misleading for the following reasons:

(i) AEZS-130 was not shown effective in the Phase 3 study according to the terms or parameters of the SPA;

(ii) Aeterna concealed that its positive AEZS-130 study results and claims of effectiveness resulted only from its throwing out the results of two AGHD patients in violation of the SPA and rerunning the statistical analysis on an incomplete dataset;

(iii) Aeterna omitted to disclose that the NDA it had filed with FDA had improperly excluded two AGHD patients from the final dataset and statistical analysis that it was relying on to support its claims that AEZS-130 was effective;

(iv) As a result of Aeterna's improper exclusion of two AGHD patients from the final dataset in violation of the SPA, it was almost certain that FDA would not approve Aeterna's NDA for AEZS-130.

54. On November 5, 2013, Aeterna submitted a New Drug Application for AEZS-130 with the FDA.

THE TRUTH EMERGES

55. On November 6, 2014, Aeterna announced that the FDA declined to approve the NDA for AEZS-130, because the Phase 3 trial did not actually meet the objectives outlined in the SPA. The press release states in relevant part:

> Aeterna Zentaris Inc. (NASDAQ: AEZS, TSX: AEZ) (the "Company") today announced that the Company has received a Complete Response Letter ("CRL") from the U.S. Food and Drug Administration ("FDA") for its New Drug Application ("NDA") for Macrilen ™ (macimorelin),

> a novel orally-active ghrelin agonist, for use in evaluating adult growth hormone deficiency ("AGHD"). ***Based on its review, the FDA has determined that the NDA cannot be approved in its present form.***
>
> The CRL mentions that ***the planned analysis of the Company's pivotal trial did not meet its stated primary efficacy objective as agreed to in the Special Protocol Assessment agreement letter between the Company and the FDA.*** The CRL further mentioned issues related to the lack of complete and verifiable source data for determining whether patients were accurately diagnosed with AGHD. The FDA concluded that, "in light of the failed primary analysis and data deficiencies noted, the clinical trial does not by itself support the indication." ***To address the deficiencies identified above, the CRL states that the Company will need to demonstrate the efficacy of macimorelin as a diagnostic test for growth hormone deficiency in a new, confirmatory clinical study.*** (emphasis added).

56. Aeterna issued this press release at 7 am on November 6, 2014, before the market opened. This adverse news that AEZS-130 had not proven effective in accordance with the parameters of the SPA, contrary to Aeterna's Class Period statements, caused Aeterna's stock to open at $0.63 per share, a decline of more than 50% from the previous day's closing price of $1.29 per share.

57. On November 7, 2014, Defendant Dodd revealed on a conference call with securities analysts that AEZS-130 only met the SPA's objectives when data from the Phase 3 study is manipulated in violation of the SPA. Specifically, AEZS-130 was only shown effective when results from two previously-confirmed AGHD patients who Aeterna later asserted did not really have confirmed AGHD

were excluded from analysis, and "when the patients who did not have confirmed AGHD were included, [AEZS-130] did not meet its primary endpoint."

58. Indeed, Aeterna could only achieve the SPA objectives for AEZS-130 when data from two patients were thrown out – in violation of the protocol and statistical analysis plan agreed to in the SPA.

59. With the benefit of Defendant Dodd's statements on the November 7, 2014 conference call, it becomes apparent exactly what improper manipulations Aeterna undertook to falsely manufacturer its claims of efficacy for AEZS-130. Aeterna's Form 20-F for the year 2011 states: "***Of the 53 AGHD subjects enrolled, 52 received AEZS-130, and 50 who had confirmed AGHD prior to study entry were included in this analysis, along with 48 controls.***" This statement indicates that only 50 of the 52 AGHD subjects that received AEZS-130 were included in the final statistical analysis submitted to the FDA.[1] Only with the benefit of Dodd's statements on the November 7, 2014 conference call is this discernible.

60. Dodd's statements on the conference call make clear that the FDA believed that Aeterna's exclusion of these two AGHD subjects from the final data analysis was a clear violation of the clinical protocols and the statistical analysis

[1] A published paper describing the AEZS-130 Phase 3 study indicates that of the 53 AGHD subjects enrolled in the study, one dropped out prior to receiving AEZS-130 due to collapsed veins.

plan agreed to in the SPA. The FDA made its position clear to Aeterna in the pre-NDA meeting – before Aeterna submitted its NDA. Thus, Aeterna had no reason to expect that the FDA would approve the NDA.

61. Because the SPA included clear rules about which subjects should and should not be included in the data analysis, Aeterna knowingly and intentionally violated the SPA's statistical analysis plan when it decided, without obtaining approval from the FDA, to exclude the results of two patients from the data analysis of AEZS-130's Phase 3 study. Aeterna only decided to exclude two AGHD subjects after it first ran the statistical analysis plan according to the SPA. When the study failed to meet the primary endpoints for efficacy under the required analysis, Aeterna decided to exclude these two patient's results and run a new analysis using the pretext that these two patients should not have been included in the Phase 3 study at all.

62. Dodd's excuse for throwing out results was that "not all patients classified as AGHD and enrolled in this during the initial phase of the study conducted by Ardana in fact met the protocol specified disease definition." Therefore, "such patients were excluded from analysis resulting in a dataset that we consider to be most appropriate for determination of the diagnostic utility of [AEZS-130]."

63. Dodd's explanation that Ardana misclassified two patients as having AGHD and that it was not until completion of the Phase 3 study and after the statistical analysis was complete that Aeterna learned of the misclassification is a false exculpatory statement. On four separate occasions, there was verification that all patients enrolled in the Phase 3 trial met the inclusion and exclusion criteria and were properly classified:

- Shortly after each newly enrolled subject entered the Phase 3 clinical trial, a clinical trial monitor visited each trial site and carefully reviewed the eligibility of each newly enrolled subject to ensure each subject was properly classified and met the inclusion and exclusion criteria. This is the specific task of a clinical trial monitor during their first visit to a clinical site after a new subject is enrolled in a clinical trial;

- During Aeterna's due diligence process prior to acquiring the rights to AEZS-130 from Ardana and taking over responsibilities for the Investigational New Drug (IND) program from Ardana. Indeed, Dodd admitted on the November 7, 2014 conference call that Aeterna carefully evaluated the patient data before taking over the study;

- During the process of negotiating the SPA with the FDA, Aeterna and the FDA did a thorough review of the enrolled patient data in

order to determine the protocol and SAP for the completion of the Phase 3 trial; and

- During Aeterna's quality control process just before data lock (i.e. the point at the conclusion of a clinical trial when no new patient data can be added or changed prior to undergoing the requested statistical analysis to support an NDA), it carefully reviewed the patient data.

64. Dodd's excuse is also meaningless. Because the SPA is a binding agreement that cannot be unilaterally changed, Aeterna needed to seek permission from the FDA and mutually agree to modify the SPA before throwing out two subjects' results from its Phase 3 study.

65. Aeterna's throwing out results from the two patients was in clear violation of the SPA and its statistical analysis plan. Aeterna's numerous statements during the Class Period that the Phase 3 trial for AEZS-130 was conducted in accordance with the parameters of the SPA and proved effective according to the statistical analysis plan set forth in the SPA were therefore false and misleading.

66. AEZS-130 was only "effective" if Aeterna cheated - by throwing out data that did not conform to the results it wanted.

ADDITIONAL SCIENTER ALLEGATIONS

67. After completing the Phase 3 study and prior to filing the NDA for AEZS-130, Aeterna held a pre-NDA meeting with the FDA. Aeterna's August 30, 2011 press release announcing the completion of the Phase 3 study stated that Aeterna was "preparing for a pre-New Drug Application (NDA) meeting with the U.S. Food and Drug Administration (FDA) in the upcoming months, which would be followed by the filing of a NDA for the registration of AEZS-130 in the United States."

68. During the pre-NDA meeting, Aeterna informed the FDA that it excluded data from two patients who did not have confirmed AGHD. The FDA disagreed with Aeterna that it was appropriate to exclude these two patients. Defendant Dodd admitted on the November 7, 2014 conference call that: "[The FDA] believe that if you have been inappropriately classified, then those data still belong in that group where they shouldn't have been classified...***and so we've had a lot of discussions with them*** and we will follow up now that we have their decision[.]"

69. Despite having been informed by the FDA at the pre-NDA meeting that it was inappropriate to exclude two patients, Aeterna nevertheless went ahead and filed the NDA for AEZS-130, knowing that the FDA disagreed with the robustness

of Aeterna's data and its analyses, that it violated the SPA and that the NDA would almost certainly be denied.

70. In addition, it is uniformly unacceptable under industry custom and practice for an IND sponsor to change the final dataset after data lock and exclude two study subjects from the final analysis, thereby changing the statistical analysis plan. This is a clear violation of the clinical trial protocol. Defendants were well aware that the FDA would never approve an NDA supported by a statistical analysis that so clearly violated the previously agreed upon study protocol.

71. Aeterna filed the NDA for AEZS-130 despite knowing that it would almost certainly be denied because Aeterna was desperate for funds to stay afloat and wanted to raise money to fund the developmental stages of its various drugs under development. By announcing positive results for the AEZS-130 Phase 3 trial, Aeterna made investors believe that the FDA would approve an NDA for AEZS-130 and Aeterna would thereby earn substantial profits and the value of its stock would rise accordingly. It didn't matter if the FDA ultimately rejected the NDA for AEZS, so long as Aeterna was able to continue to sell stock and fund operations. Therefore, Defendants made misrepresentations about AEZS-130 to enable the Company to conduct numerous rounds of financing with investors, raising more than $70 million

from 2012 to 2014.[1] Offerings during the Class Period included, but were not limited to, the following::

(a) October 12, 2012: The Company announced the completion of a public offering of 6.6 million units consisting of one share of common stock and 0.45 of a 5 year warrant to purchase one common share at $3.45 per share. The offering generated net proceeds of approximately $15.2 million for the Company.

(b) May 21, 2013: The Company announced its entry into an "At-Market Issuance" agreement with MLV & Co. LLC for the Company, in its discretion, to sell a maximum of 2.5 million shares of common stock, up to an aggregate value of $4.6 million.

(c) July, 30, 2013: The Company announced the completion of a direct offering to certain institutional investors which garnered net proceeds of approximately $7 million.

(d) November 25, 2013: The Company announced the completion of a public offering of 13.1 million units consisting of one share of common stock and one whole 5 year warrant to purchase one common share at $1.60 per share. The offering generated net proceeds of approximately $13.7 million for the Company.

[1] Source: Aeterna's Form 20-F for the year 2014.

(e) January 14, 2014: The Company announced the completion of a public offering of 11 million units consisting of one share of common stock and 0.8 of a 5 year warrant to purchase one common share at $1.25 per share. The offering generated net proceeds of approximately $12.2 million for the Company.

(f) March 28, 2014: The Company announced that the SEC had declared Aeterna's shelf registration filed on Form F-3 effective, allowing the Company to sell up to $50 million in common shares in one or more "at-the-market" offerings during a 36 month period.

72. A review of the Aeterna's SEC filings shows that a number of the Individual Defendants disposed of a substantial amount of their direct holdings AEZS common stock during the Class Period as follows:

(a) Defendant Engel owned 117,779 shares of common stock as of March 27, 2012 and only 33,333 shares as of December 31, 2012. Accordingly, without accounting for any options exercised or other related dispositions, defendant Engel sold at least 84,446 shares of stock or approximately 72% of his holdings during that period.

(b) Defendant Turpin owned 21,250 shares of common stock as of March 27, 2012 and only 3,451 shares as of December 31, 2013. Accordingly, without accounting for any options exercised or other related dispositions, defendant Turpin

sold at least 17,799 shares of stock or approximately 84% of his holdings during that period,

73. The Individual Defendants' scienter is further demonstrated by their senior level positions at Aeterna and access to material, non-public information concerning the actual results of Phase 3 trial of AEZS-130.

APPLICABILITY OF PRESUMPTION OF RELIANCE:

Fraud-on-the-Market Doctrine

74. At all relevant times, the market for Aeterna common stock was an efficient market for the following reasons, among others:

(a) Aeterna's stock met the requirements for listing, and is listed and actively traded on the NASDAQ, an highly efficient and automated market;

(b) During the class period, on average, over several hundreds of thousands of shares of Aeterna stock were traded on a weekly basis, demonstrating a very active and broad market for Aeterna stock and permitting a *very strong* presumption of an efficient market;

(c) As a regulated issuer, Aeterna filed periodic public reports with the SEC and was covered by multiple analysts;

(d) Aeterna regularly communicated with public investors via established market communication mechanisms, including through regular disseminations of

press releases on the national circuits of major newswire services and through other wide-ranging public disclosures, such as communications with the financial press and other similar reporting services;

(e) More than twenty NASDAQ member firms were active market-makers in Aeterna stock at all times during the Class Period; and

(f) Unexpected material news about Aeterna was rapidly reflected and incorporated into the Company's stock price during the Class Period.

75. As a result of the foregoing, the market for Aeterna common stock promptly digested current information regarding Aeterna from all publicly available sources and reflected such information in Aeterna's stock price. Under these circumstances, all purchasers of Aeterna common stock during the Class Period suffered similar injury through their purchase of Aeterna common stock at artificially inflated prices, and a presumption of reliance applies.

Affiliated Ute

76. Neither Plaintiffs nor the Class need prove reliance – either individually or as a class because under the circumstances of this case, positive proof of reliance is not a prerequisite to recovery, pursuant to ruling of the United States Supreme Court in *Affiliated Ute Citizens of Utah v. United States*, 406 U.S. 128 (1972). All that is necessary is that the facts withheld be material in the sense that a

reasonable investor might have considered the omitted information important in deciding whether to buy or sell the subject security.

PLAINTIFFS' CLASS ACTION ALLEGATIONS

77. Plaintiff brings this action as a class action pursuant to Federal Rules of Civil Procedure 23(a) and (b)(3) on behalf of a Class, consisting of all persons who purchased the common stock of Aeterna during the Class Period and who were damaged thereby. Excluded from the Class are Defendants, the officers and directors of the Company at all relevant times, members of their immediate families and their legal representatives, heirs, successors or assigns and any entity in which defendants have or had a controlling interest.

78. The members of the Class are so numerous that joinder of all members is impracticable. Throughout the Class Period, Aeterna's securities were actively traded on the NASDAQ. While the exact number of Class members is unknown to Plaintiffs at this time and can only be ascertained through appropriate discovery, Plaintiffs believe that there are at least hundreds of members in the proposed Class. Members of the Class may be identified from records maintained by Aeterna or its transfer agent and may be notified of the pendency of this action by mail, using a form of notice customarily used in securities class actions.

79. Plaintiffs' claims are typical of the claims of the members of the Class, as all members of the Class are similarly affected by Defendants' wrongful conduct in violation of federal law that is complained of herein.

80. Plaintiffs will fairly and adequately protect the interests of the members of the Class and has retained counsel competent and experienced in class and securities litigation.

81. Common questions of law and fact exist as to all members of the Class and predominate over any questions solely affecting individual members of the Class. Among the questions of law and fact common to the Class are:

(a) whether the federal securities laws were violated by Defendants' acts as alleged herein;

(b) whether statements made by Defendants to the investing public during the Class Period misrepresented material facts about the business, operations and management of Aeterna;

(c) whether the Individual Defendants caused Aeterna to issue false and misleading statements during the Class Period;

(d) whether Defendants acted knowingly or recklessly in issuing false and misleading financial statements;

(e) to what extent the members of the Class have sustained damages and the proper measure of damages.

82. A class action is superior to all other available methods for the fair and efficient adjudication of this controversy since joinder of all members is impracticable. Furthermore, as the damages suffered by individual Class members may be relatively small, the expense and burden of individual litigation make it impossible for members of the Class to redress individually the wrongs done to them. There will be no difficulty in the management of this action as a class action.

FIRST CLAIM

Violation of Section 10(b) Of The Exchange Act Against and Rule 10b-5 Promulgated Thereunder Against All Defendants

83. Plaintiffs repeat and reallege each and every allegation contained above as if fully set forth herein.

84. This claim is brought against all Defendants.

85. During the Class Period, Defendants carried out a plan, scheme and course of conduct that was intended to and, throughout the Class Period, did: (1) deceive the investing public, including Plaintiffs and other Class members, as alleged herein; and (2) cause Plaintiffs and other members of the Class to purchase Aeterna common stock at artificially inflated prices. In furtherance of this unlawful

scheme, plan and course of conduct, Defendants, and each of them, took the actions set forth herein.

86. Defendants (a) employed devices, schemes, and artifices to defraud; (b) made untrue statements of material fact and/or omitted to state material facts necessary to make the statements not misleading; and (c) engaged in acts, practices, and a course of business that operated as a fraud and deceit upon the purchasers of the Company's common stock in an effort to maintain artificially high market prices for Aeterna common stock in violation of Section 10(b) of the Exchange Act and Rule 10b-5 thereunder. All Defendants are sued either as primary participants in the wrongful and illegal conduct charged herein or as controlling persons as alleged below.

87. Defendants, individually and in concert, directly and indirectly, by the use, means or instrumentalities of interstate commerce and/or of the mails, engaged and participated in a continuous course of conduct to conceal adverse material information about the business, operations and future prospects of Aeterna as specified herein.

88. These Defendants employed devices, schemes and artifices to defraud, while in possession of material adverse non-public information and engaged in acts, practices, and a course of conduct as alleged herein in an effort to assure investors of

Aeterna's value and performance and continued substantial growth, which included the making of, or participation in the making of, untrue statements of material facts and omitting to state material facts necessary in order to make the statements made about Aeterna and its business operations and future prospects in the light of the circumstances under which they were made, not misleading, as set forth more particularly herein, and engaged in transactions, practices and a course of business that operated as a fraud and deceit upon the purchasers of Aeterna common stock during the Class Period.

89. Each of the Defendants' primary liability, and controlling person liability, arises from the following facts: (1) the Individual Defendants were high-level executives, directors, and/or agents of the Company during the Class Period and members of the Company's management team or had control thereof; (2) each of these defendants, by virtue of his or her responsibilities and activities as a senior officer and/or director of the Company, was privy to and participated in the creation, development and reporting of the Company's financial condition; (3) each of these defendants enjoyed significant personal contact and familiarity with the other defendants and was advised of and had access to other members of the Company's management team, internal reports and other data and information about the Company's business and operations at all relevant times; and (4) each of these

defendants was aware of the Company's dissemination of information to the investing public which they knew or recklessly disregarded was materially false and misleading.

90. Defendants had actual knowledge of the misrepresentations and omissions of material facts set forth herein, or acted with reckless disregard for the truth in that they failed to ascertain and to disclose such facts, even though such facts were available to them. Such Defendants' material misrepresentations and/or omissions were done knowingly or recklessly.

91. As a result of the dissemination of the materially false and misleading information and failure to disclose material facts, as set forth above, the market price of Aeterna common stock was artificially inflated during the Class Period. In ignorance of the fact that market prices of Aeterna's publicly-traded common stock were artificially inflated, and relying directly or indirectly on the false and misleading statements made by Defendants, or upon the integrity of the market in which the common stock trades, and/or on the absence of material adverse information that was known to or recklessly disregarded by Defendants but not disclose in public statements by Defendants during the Class Period, Plaintiffs and the other members of the Class acquired Aeterna common stock during the Class Period at artificially high prices and were or will be damaged thereby.

92. At the time of said misrepresentations and omissions, Plaintiffs and other members of the Class were ignorant of their falsity, and believed them to be true. Had Plaintiffs and the other members of the Class and the marketplace known the truth regarding Aeterna's business operations and future prospects, which were not disclosed by defendants, Plaintiff and other members of the Class would not have purchased or otherwise acquired their Aeterna common stock, or, if they had acquired such common stock during the Class Period, they would not have done so at the artificially inflated prices that they paid.

93. By virtue of the foregoing, Defendants have violated Section 10(b) of the Exchange Act, and Rule 10b-5 promulgated thereunder.

94. As a direct and proximate result of Defendants' wrongful conduct, Plaintiffs and the other members of the Class suffered damages in connection with their respective purchases and sales of the Company's common stock during the Class Period.

95. This action was filed within two years of discovery of the fraud and within five years of each Plaintiff's purchases of securities giving rise to the cause of action.

SECOND CLAIM
Violation of Section 20(a) Of The Exchange Act
Against the Individual Defendants

96. Plaintiffs repeat and reallege each and every allegation contained above as if fully set forth herein.

97. By virtue of their high-level positions, agency, and their ownership and contractual rights, participation in and/or awareness and/or intimate knowledge of the misleading statements disseminated to the investing public, the Individual Defendants had the power to influence and control, and did influence and control, directly or indirectly, the decision-making of the primary violator, including the content and dissemination of the various statements that Plaintiffs contend are false and misleading. In particular, each Individual Defendant had the power to control or influence the particular transactions and statements giving rise to the securities violations as alleged herein, and exercised the same.

98. As set forth above, Aeterna violated Section 10(b) and Rule 10b-5 by their acts and omissions as alleged in this Complaint.

99. By virtue of their positions as controlling persons, the Individual Defendants are liable pursuant to Section 20(a) of the Exchange Act. As a direct and proximate result of Defendants' wrongful conduct, Plaintiffs and other members of the Class suffered damages in connection with their purchases of the Company's common stock during the Class Period.

100. This action was filed within two years of discovery of the fraud and within five years of each Plaintiff's purchases of securities giving rise to the cause of action.

WHEREFORE, Plaintiffs pray for relief and judgment, as follows:

101. Determining that this action is a proper class action, certifying Plaintiffs as class representative under Rule 23 of the Federal Rules of Civil Procedure and Plaintiffs' counsel as Class Counsel;

102. Awarding compensatory damages in favor of Plaintiffs and the other Class members against all defendants, jointly and severally, for all damages sustained as a result of defendants' wrongdoing, in an amount to be proven at trial, including interest thereon;

103. Awarding Plaintiffs and the Class their reasonable costs and expenses incurred in this action, including counsel fees and expert fees; and

104. Such other and further relief as the Court may deem just and proper.

JURY TRIAL DEMANDED

Plaintiffs hereby demand a trial by jury.

April 10, 2015

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CERTIFICATE OF SERVICE

I hereby certify that on this 10th day of April 2015 a true and correct copy of the foregoing document was served by CM/ECF to the parties registered to the Court's CM/ECF system.

/s/ James E. Cecchi